

Complete Summary

GUIDELINE TITLE

Perinatal viral and parasitic infections.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Perinatal viral and parasitic infections. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Sep. 13 p. (ACOG practice bulletin; no. 20). [131 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Perinatal viral and parasitic infections. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1993 Feb. (ACOG educational bulletin number 177).

According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important information has been released.

On September 20, 2005, the U.S. Food and Drug Administration announced on their Web site that the only U.S.-licensed manufacturer of varicella zoster immune globulin (VZIG) (Massachusetts Public Health Biologic Laboratories, Boston, MA) has discontinued manufacture of VZIG, which is indicated for patients in need of passive immunization to prevent severe varicella zoster infection.

On February 8, 2006, the FDA noted that the supply of the licensed VZIG product is nearly depleted. However, an investigational (not licensed) VZIG product (manufactured and currently under development by Cangene Corporation Winnipeg, Canada) is available under an investigational new drug application (IND) protocol. This product may be requested through FFF Enterprises (Temecula, CA) for individuals who have been exposed to varicella and who are at increased risk of complications from varicella. See the [FDA Web site](#) for more information.

In addition, the Centers for Disease Control and Prevention have released information regarding this new product (VariZIG™). See the [CDC Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Viral and parasitic infections during pregnancy, including cytomegalovirus, parvovirus B19, varicella Zoster virus, and toxoplasmosis

GUIDELINE CATEGORY

Counseling
Diagnosis
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To describe perinatal viral and parasitic infections, their modes of transmission, and their maternal and fetal effects, and to offer guidelines for counseling about and management of these infections during pregnancy

TARGET POPULATION

Pregnant women with or at risk of viral or parasitic infection

INTERVENTIONS AND PRACTICES CONSIDERED

Cytomegalovirus (CMV)

Prevention

Counseling of pregnant women regarding methods to prevent acquisition of CMV, including careful handling of potentially infected articles, thorough hand washing, and avoidance of high risk behaviors

Screening/Diagnosis

1. Maternal testing (culture, polymerase chain reaction [PCR], serologic testing) (Routine screening not recommended)
2. Fetal testing (amniotic fluid cultures, PCR, fetal blood sampling, ultrasound)

Treatment

Antiviral treatment with ganciclovir or foscarnet and a live attenuated vaccine using the Towne 125 strain were discussed but not recommended.

Parvovirus B19

Screening/Diagnosis

1. Maternal testing (serologic testing, enzyme-linked immunosorbent assay [ELISA], radioimmunoassay, Western blot, electron microscopy)
2. Fetal testing (isolation of viral particles in abortuses or placental specimens, PCR, ultrasound, ultrasonography to monitor for hydrops fetalis in pregnant women with acute parvovirus, serial ultrasound, fetal blood sampling in fetuses with evidence of hydrops)

Treatment

Intrauterine transfusion for fetuses with evidence of hydrops

Varicella Zoster Virus (VZV)

Prevention

1. Varicella vaccine for nonpregnant women of childbearing age with no history of varicella infection
2. Varicella-zoster immune globulin (VZIG) for pregnant women seronegative for VZV who are exposed to chickenpox

Screening/Diagnosis

1. Maternal testing (clinical evaluation, ELISA)
2. Fetal testing (ultrasound)

Treatment

1. Oral acyclovir
2. Intravenous acyclovir for pregnant women who develop pneumonia along with varicella
3. VZIG for infants born to women who develop varicella between 5 days before and 2 days after delivery
4. Intravenous acyclovir for infants who develop varicella in the first 2 weeks of life.

Toxoplasmosis

Prevention

Counseling of pregnant women regarding methods to prevent acquisition of toxoplasmosis

Screening/Diagnosis

1. Maternal testing (serologic testing, antibody assays) (routine screening not recommended)
2. Fetal testing (ultrasound, fetal blood sampling, PCR)

Treatment

1. Spiramycin for pregnant women who acquire toxoplasmosis
2. A combination of pyrimethamine, sulfadiazine, and folinic acid, alternating with spiramycin, for fetal toxoplasmosis

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Maternal and fetal morbidity and mortality
- Maternal-fetal impact of infection
- Effect of treatments for viral and parasitic infections during pregnancy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources were used to conduct a literature search to locate relevant articles published between January 1985 and January 2000. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II -1 Evidence obtained from well-designed controlled trials without randomization

II -2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II -3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Pregnant women who are seronegative for varicella zoster virus (VZV) and exposed to chickenpox should receive varicella-zoster immune globulin (VZIG).
- Pregnant women who develop chickenpox should be treated with oral acyclovir to minimize maternal symptoms; if pneumonia develops, they should be treated with intravenous acyclovir.
- Pregnant women who have acute parvovirus B19 infection during pregnancy should be monitored with serial ultrasound examinations for at least 10 weeks following infection for the presence of hydrops fetalis.
- Fetuses with evidence of hydrops should undergo fetal blood sampling and transfusion as needed.
- Pregnant women who acquire toxoplasmosis should be treated with spiramycin. When diagnosed, fetal toxoplasmosis should be treated with a combination of pyrimethamine, sulfadiazine, and folinic acid, alternating with spiramycin.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Routine serologic screening of all pregnant women for cytomegalovirus (CMV) and toxoplasmosis is not recommended.
- Nonpregnant women of reproductive age who have no history of varicella infection should be offered varicella vaccine.
- The diagnosis of toxoplasmosis should be confirmed by a reliable reference laboratory.
- Pregnant women exposed to parvovirus B19 should have serologic screening performed to determine if they are at risk for seroconversion.
- Pregnant women should be counseled about methods to prevent acquisition of cytomegalovirus or toxoplasmosis during pregnancy.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II -1 Evidence obtained from well-designed controlled trials without randomization

II -2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II -3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Appropriate management of perinatal viral and parasitic infections

Benefits of Specific Interventions

- Counseling: The greatest impact obstetrician-gynecologists can have on reducing cytomegalovirus (CMV) disease is by educating patients about preventive measures. A study in Belgium demonstrated a 63% reduction in the rate of maternal toxoplasmosis infection after institution of an educational program that recommended avoiding eating undercooked or raw meat, wearing gloves when working with soil, and avoiding caring for cats unless they are strictly "indoor cats" whose food is rigidly controlled.
- Acyclovir for varicella zoster: Oral acyclovir, if instituted within 24 hours of the rash, has been shown to reduce the duration of new lesion formation and the total number of new lesions and to improve constitutional symptoms in children, adolescents, and adults. Oral acyclovir appears to be safe and can be prescribed for pregnant women if lesions develop. Intravenous acyclovir may reduce maternal morbidity and mortality associated with varicella pneumonia.
- Varicella-zoster immune globulin (VZIG): If exposure to varicella zoster virus (VZV) occurs, prophylactic intervention with VZIG early in the incubation period can prevent or attenuate the disease manifestations of VZV in susceptible contacts at high risk from this infection.
- Treatment for toxoplasmosis: Treatment of the pregnant woman with acute toxoplasmosis reduces but does not eliminate the risk of congenital infection. Spiramycin may reduce the risk of fetal transmission by 60%. If fetal infection

is established, pyrimethamine, sulfonamides, and folinic acid are added to the regimen because they more effectively eradicate parasites in the placenta and in the fetus than spiramycin alone. With treatment, even early fetal infection with toxoplasmosis can result in successful pregnancy outcomes.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Perinatal viral and parasitic infections. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Sep. 13 p. (ACOG practice bulletin; no. 20). [131 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Sep (reviewed 2005)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Perinatal viral and parasitic infections. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1993 Feb. (ACOG educational bulletin number 177).

According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004. This summary was updated by ECRI on March 3, 2006 following the FDA advisory on varicella zoster immune globulin (VZIG).

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 10/9/2006